

Kline, Cliff

From: Free, Donna
Sent: Monday, January 03, 2005 2:20 PM
To: Kline, Cliff
Subject: FW: response to Tables 13.1 and 13.3.1

-----Original Message-----

From: Free, Donna
Sent: Friday, November 19, 2004 10:14 AM
To: 'Dawisha, Sahar'
Cc: 'Allen, Samie Niver'; Michael, Maher; Kline, Cliff
Subject: response to Tables 13.1 and 13.3.1

Hi Sahar,

Attached please find our response to your questions regarding MRI accounting tables 13.1 and 13.3.1. Please let us know if you require additional information.

Thanks and have a nice weekend.

Donna

1/3/2005

2005-11-21 10:14 AM - 11-2-04 10:14 AM

Response to FDA question on Tables 13.1 and 13.3.1 – Number of Patients who had MRI scans after Explant of Original Core Gel Implants

Patient as the patient involved in the question on Tables 13.1 and 13.1, where there is confusion in the number of patients who had MRIs after removal of their original Core Gel implants.

In Table 13.1 she is counted in the N=9, where 9 is the number of patients who had MRIs after their original Core Gel implants were removed.

In Table 13.3.1, at 1 year, she is not included in the N=8, where the 8 are the patients who had MRIs after their original Core Gel was removed. Instead at 1 year, she is accounted for in the row "Missed Follow-up Visit," as she never came in for her 1 year MRI. At 2 years, in Table 13.3.1, she is counted in the N=11, where 11 is the number of patients who had MRIs after their original Core Gel implants were removed. Please note that the patients discussed in footnote D (8 and 11 patients) should not have had an MRI, as they had their original Core Gel implants removed.

Below is further summary information providing dates of surgery and MRI scans, and the table below details the patients who were excluded from analysis because the MRI scans occurred after explantation of their original Core Gel implants.

Patient

Date of surgery: 9/5/2001

Date of 1 year scan: she did not come in for her scan

Date of 2 year scan: 8/27/2003

Date of explant: 6/26/2002

**Patients Excluded from Analysis
because they had MRI scan after
Original Core Gel Implants Explanted**

Patient	13.1	13.3.1 Year 1	13.3.1 Year 2
	X	X	X
	X	X	X
	X	X	X
	X	X	X
	X	X	X
	X	X	
			X
	X		X
			X
	X	X	
	X	X	X
			X
			X
Total	9	8	11